Surya Manickam
Pediatric Resident, PGY2
Principal Investigators: Lisa Saiman, MD
Other Investigators: Irene Frantzis, MD; Anshu Paul, MD; Kyra Solowey, MD; Eliza Gentzler, MD; Sandhya Brachio, MD; Candace Johnson, MD
Date: August 6, 2021

Neonatal Infection Prevention: A Retrospective Epidemiological Look at Healthcare Associated Blood-Stream Infections in the NICU

Study Purpose and Rationale

Healthcare associated infections are a major cause of mortality and morbidity in neonatal intensive care units (NICUs). Their prevalence is noted to be between 6-40% in the United States, with higher proportions among very low birth weight infants[1-4] and 7-20% across the globe[5-10].
Among healthcare associated infections in the NICU, bloodstream infections are the most common, accounting for 44-73%.[2,5,6,8] There has been increasing focus and success in prevention of central line-associated bloodstream infections (CLABSIs) in the NICU. However, non-CLABSIs and factors associated with them remain an area with limited study and this could be crucial to the understanding of how to prevent these infections.

In this study we aim to:

1. Estimate the incidence of healthcare-onset bloodstream infections (HO-BSIs) over the ten year period (2009-2019)
2. Determine the potential sources of these HO-BSIs, including both CLABSI and secondary BSIs associated with infections at other body sites (non-CLABSIs). These secondary BSI include surgical site infections, skin and soft tissue infections, intra-abdominal infections, pneumonia, bone and joint, meningitis, and cardiac/intravascular infections
3. Compare characteristics of infants with CLABSI vs non-CLABSI HO-BSIs
4. Assess potential opportunities to prevent HO-BSIs
5. Determine the pathogens and their antimicrobial susceptibilities associated with HO-BSIs over the ten year period (2009-2019)

Study Design and Statistical Analysis

This is a retrospective epidemiological observational study by chart review of all infants with positive blood cultures on day of life 3 or later (per the CDC National Healthcare Safety Network definition of health care associated infections in newborns) admitted to the Columbia neonatal intensive care unit over the span of ten years, between 2009-2019. T-test or chi-squared analyses will be performed for multiple characteristics comparing infants with CLABSIs and non-CLABSIs. We will also consider using Kaplan-Meier curves and/or a Cox Proportional Hazards Model to compare prognostic measures such as time to resolution of infection by source of infection (CLABSI vs surgical site infection vs skin/soft tissue infection vs intra-abdominal infection, etc) qualified by neonatal risk factors such as gestational age, birth weight, multiples, DOL at time of infection, race/ethnicity, etc.

Study Subjects

All infants with positive blood cultures on day of life 3 or later who were admitted to the neonatal intensive care unit in the years 2009-2019. As this is a retrospective study, no subjects will be recruited.

Informed Consent of Study Subjects

This study may be considered for a waiver of consent as it fulfills the following criteria:

1. The research involves no more than minimal risk to the subjects: this is a retrospective chart review and thus involves no more than minimal risk to the subjects
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects: this is a retrospective study and will not affect the rights or welfare of the study subjects
3. The research could not practicably be carried out without the waiver or alteration: due to its retrospective nature, it would be impossible to obtain consent for all study participants and the study would be incomplete without all the study participants' data
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Confidentiality of Study Data

Our database will be maintained on a CUIMC-approved and managed server system ID #4017. Files may also be stored on the MC domain (#6692). The study database will contain a unique study ID number, MRNs, DOB, demographic data, comorbid conditions, and hospital course. Data will either be accessed on a CUIMC computer or on VPN if home computers or laptops are used. No information will be saved on local computers.

Potential Conflict of Interest

No potential conflicts of interest.

Location of the Study

This is a single-center study. All data will be obtained from the Columbia University Irving Medical Center electronic medical records.

Potential Risks

Given its retrospective nature, this study has no risks outside of a potential for breach of confidentiality.

Potential Benefits

There are no direct benefits to the participants of this study. However, society benefits from the results of this study because it may help us understand how to prevent these infections in the future.

Compensation of Subjects

No compensation will be provided to study subjects.

References

1. Brady MT. Healthcare–associated infections in the neonatal intensive care unit. Am J Infect Control 2005;33:268–75.
2. Sass L, Karlowicz MG. Healthcare-Associated Infections in the Neonate [Internet]. In: Principles and Practice of Pediatric Infectious Diseases. Elsevier; 2018 [cited 2020 Dec 17]. p. 560-566.e3.Available from: https://linkinghub.elsevier.com/retrieve/pii/B9780323401814000943
3. Stoll BJ, Hansen N. Infections in VLBW Infants: Studies From the NICHD Neonatal Research Network.
4. Stoll BJ, Hansen N, Fanaroff AA, et al. Late-Onset Sepsis in Very Low Birth Weight Neonates: The Experience of the NICHD Neonatal Research Network. PEDIATRICS 2002;110:285–91.
5. Kumar S, Shankar B, Arya S, Deb M, Chellani H. Healthcare associated infections in neonatal intensive care unit and its correlation with environmental surveillance. J Infect Public Health 2018;11:275–9.
6. Morkel G, Bekker A, Marais BJ, Kirsten G, van Wyk J, Dramowski A. Bloodstream infections and antimicrobial resistance patterns in a South African neonatal intensive care unit. Paediatr Int Child Health 2014;34:108–14.
7. Yapicioglu H, Ozcan K, Sertdemir Y, et al. HealthCare-associated Infections in a Neonatal Intensive Care Unit in Turkey in 2008: Incidence and Risk Factors, A Prospective Study. J Trop Pediatr 2011;57:157–64.
8. Crivaro V, Bogdanovi L, Triassi M, Zarrilli R. Surveillance of healthcare-associated infections in a neonatal intensive care unit in Italy during. 2015;8.
9. Zipursky AR. Central Line-Associated Blood Stream Infections and Non-Central Line-Associated Blood Stream Infections Surveillance in Canadian Tertiary Care Neonatal Intensive Care Units. J Pediatr 2010;208:13.
10. Verstraete E, Boelens J, Coen KD, et al. Healthcare-Associated Bloodstream Infections in a Neonatal Intensive Care Unit over a 20-Year Period (1992–2011): Trends in Incidence, Pathogens, and Mortality. Infect Control Hosp Epidemiol 2014;35:511–8.